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CE 0088

ZENITH TOTAL ANKLE REPLACEMENT SYSTEM

General Information

Attention Operating Surgeon

IMPORTANT Please read carefully before implanting this product

DESCRIPTION

ZENITH is a total ankle replacement system, with optimised bearing surfaces, proven bearing geometry and effective instrumentation. Titanium nitride provides optimised bearing surfaces for reduced wear, whilst dual-coating of the tibial and talar components provides secondary fixation. The deep sulcus gives good stability and reduced risk of subluxation, and the unconstrained insert allows maximum range of motion and minimum wear. The design also results in minimal bone resection. Four tibial, four talar and four bearing sizes can be combined as required for flexibility in matching patient anatomy.
Materials: Talar & tibial components – available in wrought titanium or cast cobalt chromium alloy; Meniscal component - Ultra High Molecular Weight Polyethylene; Coatings - Titanium Nitride (Ti variant only), Calcium Phosphate & Titanium

INDICATIONS

The ZENITH Total Ankle Replacement System is indicated for use in the replacement of the articulating surfaces of tibio-talar compartments of the ankle where this has been affected by primary degenerative arthritis, post traumatic degenerative arthritis or rheumatoid joint disease. Ankle arthroplasty is indicated in ankles with marked deformation and destruction, especially where sub-talar or mid-tarsal joints are involved. In addition, a patient should be considered a candidate for a total ankle arthroplasty if he or she cannot tolerate prolonged periods of immobilization as would be necessary after an ankle arthrodesis. The device is indicated for use without bone cement. The device is intended for prescription use only.

CONTRAINDICATIONS

1. Active local or systemic infection;
2. Destruction of bone stock that precludes fixation of the components;
3. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustifiable;
4. Charcot's disease;
5. Patient's age, weight or activity level that, in the surgeon's opinion, cause the prosthesis to be at high risk for failure;
6. Neurological deficiency with dynamic muscular imbalance across the ankle joint;
7. Severe deformity in which proper alignment of the ankle cannot be restored;
8. Absence of the medial and/or lateral malleoli;
9. Poor skin condition secondary to surgical scars or trauma

WARNINGS

Excessive wear or failure of the implant may result from: selection of improper components, mal-alignment or mal-positioning of the components, inadequate fixation of components, failure to remove surgical debris prior to closure. Clean gloves should be worn when handling implants. Avoid scratching or denting implant surfaces. Do not modify implants. Do not use another manufacturer's device in articulation with components of the ZENITH system. Surgeons should be familiar with the ZENITH operative technique before implanting this device. The following conditions tend to adversely affect ankle replacement implants: Obesity or excessive patient weight; sports participation and/or high activity level; alcohol and/or drug addiction. A non-functioning sub-talar joint in an active individual; Poor bone stock; Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g. diabetes, steroid usage, immunosuppressive treatments, etc.); Severe deformities of the joint; tumors of the supporting bone structures; Sensitivity, allergy or other reactions to implant materials (i.e. polyethylene or metal). This device should not be used in conjunction with bone cement.

STERILITY

ZENITH implants are supplied sterile. Check the integrity of the packaging carefully. Do not use if the packaging is open or damaged. Do not resterilise. For single use only.

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